



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,925	07/11/2003	Johann J. Neisz	239575US 25 CONT	3006
22850	7590	07/02/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/616,925	NEISZ ET AL.	
	Examiner	Art Unit	
	Samuel G Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/11/2003</u>   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 7/11/2003 has been considered. The lined through references did not include a date as required.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the repositioning means including a plurality of filaments, claim 9; more tightly woven claims 11 and 12; and a handle, claim 31 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2 and 4-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,652,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 - in line 7 "repair" should be "a pair".

Art Unit: 3736

Claims 15 and 16 – “combinations thereof” is indefinite because the applicant has not set forth the possible combinations.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 13-16, 19, 20, and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (4,979,956).

Claims 1, 5, 8, 13, 19, and 26-29 – Silvestrini teaches a sling having two surfaces –10-, two ends –14- and –16-, a support portion shown between end portion edges –28- and –30-, the ends of the support portion connect to end portions –14- and –16-. The examiner is taking suture –18- as a repositioning means.

Claims 2 and 4 – the sling is capable of performing in the manner as claimed. The recited intended use does not impart any structural differences between Silvestrini and the claimed structure.

Claim 6 – the suture is a filament.

Claim 7 – see locking stitches –24- and –28-.

Claim 14 – the sling can be synthetic, applicant's attention is invited to column 2 lines 49-61.

Art Unit: 3736

Claim 15 and 16 – the examiner is taking the coating described in column 5 line 6-16 as a medicament, a substance used in therapy.

Claim 20 – more of the suture is on the side shown in figure 1.

Claim 29 – needle 20, provides a locating and detaching the suture.

Claims 1, 2, 4-8, 13-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Tihon et al. (6,042,536).

Claims 1, 13, 14, Tihon et al teaches a sling having two surfaces, a pair of end portions, shown generally at –2- and –3-, a support portion shown generally between –2- and –3-, and repositioning means –11-. The sling can be made of silicone.

Claims 2 and 4 – the sling is capable of performing in the manner as claimed. The recited intended use does not impart any structural differences between Tihon et al and the claimed structure.

Claim 5 – applicant's attention is invited to column 3, lines 43-48.

Claim 6 – element –11- is a filament.

Claim 7 – element –11- is attached at elements –2- and –3-.

Claims 8 and 28 – element –11- can be integral with the mesh, column 3 lines 53-55.

Claims 15 and 16 – see column 3 lines 4-6.

Claim 21 – element –10- is a sheath.

Art Unit: 3736

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (4,979,956).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use more than one suture woven into the mesh as a duplication of known elements. Duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F2d.669, 124 USPQ 378 (CCPA 1960).

Claims 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tihon et al(6,042,536).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use more than one suture woven into the mesh as a duplication of known elements. Duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F2d.669, 124 USPQ 378 (CCPA 1960).

Art Unit: 3736

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tihon as applied to claim 1 above, and further in view of Trabucco (6,306,079). Tihon teaches a device as claimed but does not teach a portion of bioabsorbable material. Trabucco teaches a pubovaginal sling including a bioabsorbable portion providing a benefit to the healing of the patient after surgery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a bioabsorbable portion to provide the benefit of providing support before fibrosis and then allowing fibrosis to eliminate the problem of urethral erosion or retention.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tihon as applied to claim 1 above, and further in view of Berger (6,638,210). Tihon teaches a device as claimed but does not provide a sheath around the sling. Berger teaches a sling having a sheath -66-. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sheath as taught by Berger with the sling of Tihon to ensure that the sling of Tihon does not adhere to the tissue before it is in the correct surgical position as taught by Berger.

***Allowable Subject Matter***

Claims 11, 12, 18, 22-25, 30 and 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.



Art Unit: 3736

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 703-308-3553. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Samuel G Gilbert  
Primary Examiner  
Art Unit 3736

sgg  
June 26, 2004